MEDICAL TECHNOLOGY

Bubble Counter BC100

A Device for the Detection of Micro Bubbles in Streaming Fluids

User Manual

Gesellschaft für Angewandte Medizinische Physik und Technik mbH (GAMPT mbH)
Hallesche Straße 99F
06217 Merseburg
Germany

Fon: +49 (0) 3461-278 691- 0
Fax: +49 (0) 3461-278 691- 101
email: info@gampt.de

www.gampt.de

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Hallesche Strasse 99F • 06217 Merseburg
Fon 034601/278 691-0 • Fax 03461/278 691-101
info@gampt.de • www.gampt.de

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1. General safety instructions

Intended purpose:
The BC100 serves for the non-invasive measurement of the air bubble activity in the blood of the extra corporeal circulation.

Short description:
With the Bubble Counter BC100 it is possible to determine the number and the size of micro bubbles in the blood of the extra corporeal circulation (ECC). The measurement is done with two independently working non-invasive probes from the outside of the tube. The measurement is based on a self-calibrating Ultrasound Doppler system so that parameters like tube material, blood concentration and flow speed have no influence. Micro bubbles with diameters of 5– 500 µm are detected and their sizes are displayed in a histogram.
With the software BCView the BC100 can be used for the supervision of the bubble activity during the whole ECC, as well as for the judgement of the achievement parameters of single components of the ECC concerning the bubble activity or filtering. The recorded measuring data and corresponding patient's data are administered in a database system and can be analysed with the help of extensive tools.

Please read the safety instructions carefully before using the unit and the ultrasound probe.

- The unit should only be opened by technical service. Always unplug the device before opening.
- Observe that the ventilation outlet slits are never blocked to avoid the device from warming up.
- Make sure the device cable is plugged into a duly installed socket and to use the required power supply and fuses specified on the control unit.
- Never insert objects into the outlets in order to avoid for a short circuit or electric shock.
- Before clamp on the probe to the tube give a thin gelfilm to the active inner surfaces of the probe. Especially for the small probes (1/4") use only a tiny bit. It is to avoid, that the gel makes a direct contact between the both inner surfaces of the probe.
- **Please notice the special user and safety instructions in the chapters highlighted by an arrow and written in cursive.**

The BC100 is tested for the use of the following tubes:

Raumedic ECC	Terumo Xcoat 101470
Sorin 019062	Terumo Xcoat 101465
Sorin 019061	Terumo IT 1-2-087
Sorin 019061 B	Terumo IT 1-2-084
Sorin 019061 R	Terumo USP 1-2-018
	Intersept V

The calibration for the different probe size will be done with the following tube sizes:

tube ID diameter:	1/2''	3/8''	1/4''
tube thickness:	3/32"	3/32"	1/16"

2. Introduction

The Bubble Counter BC100 from GAMPT mbH made in Merseburg, Germany, is a measuring device for the detection of micro bubbles in streaming fluids.

Figure 1: Bubble Counter BC100 with 2 probes

During open heart surgery micro bubbles will be generated continuously. Size and number of bubbles depend on the operation process and the necessary manipulations at the heart-lung-machine. The risk of complication like a gas embolism increases if too many bubbles enter the blood circulation of the patient. Even though heart lung machines have arterial filters it is necessary to observe the extra corporal circulation.

The self calibrating Bubble Counter BC 100, based on the ultrasound Doppler method, is able to detect and classify micro bubbles down to a size of 5 µm. Because of its parameters the device is appropriate to the clinical use for controlling of heart lung machine as well as the laboratory investigations on filter systems and oxygenators.

3. Components, Installation and Handling

3.1. BC100 Measuring Device, Front Side

Figure 2: Front panel with control and display components

The device should be used in a sloped position using the handle (see figure 1) to ensure an optimum ventilation. Use the power button (10) to switch on the device. The switch lights up when the device is on.

With the switches (1) and (3) the measurement range of the two channels can be changed between 5-250µm and 10-500µm. This will change the amplification of the bubble signal in the electronic. The measurement range will be detected automatically by the software (see chapter software) to enable an exact correlation between measured signal and bubble size.
With the switches (7) and (9) the light bar (2,4) can be changed between the presentation of the reference signal and the presentation of the bubble signal. The selected signal is marked by a yellow LED light.

- *The display serves only for a rough orientation. Exact results can only be obtained by the software. The bubble signal on the display is not absorption corrected and the reference signal only roughly calibrated.*

With switch (11) the acoustical bubble signal can be changed between channel 1 (red) and channel 2 (green). In the middle position the audio system is switched off. With the turning knob (5) the volume can be adjusted.

- *The audio signal serves only for orientation and control purposes during the measurement because its amplitude depends on the frequency and might falsify the bubble size. The speaker driver can cause noises and disturb the detection barrier. For exact measurements it is recommended to keep the switch in the middle position (audio off).*

The measuring probes are connected at inputs (6) and (8). It is recommend to keep the allocation of the colour marked probes because the sensitivity differences between the probes were calibrated.

3.2. BC100 Measuring Device, Rear Side

Figure 3: rear side with connections

Attach the power cable to the power socket on rear side of the device and the data cable from USB port of the device to the computer.

- *Notice! Please follow the voltage and power specifications on the device!*

- *To keep the noise level and the detection barriers low, find the correct cable position. Keep the sensor cable away from power and PC cables.*

3.3. Ultrasound Sensors

Figure 4: Ultrasound Sensor for measuring of 3/8“ tubes.

The ultrasound sensors of the GAMPT mbH enable self calibrating measurements of streaming fluids in 3/8“ tubes. With the locking device the probe can be fixed around the tube easily.

- *For a better sound coupling place ultrasound gel between sensor and tube.*

- *The probes can deform the tube. Therefore do not place the probes directly behind each other and do not place them twisted for this might cause swirls in the tube.*

4. Software

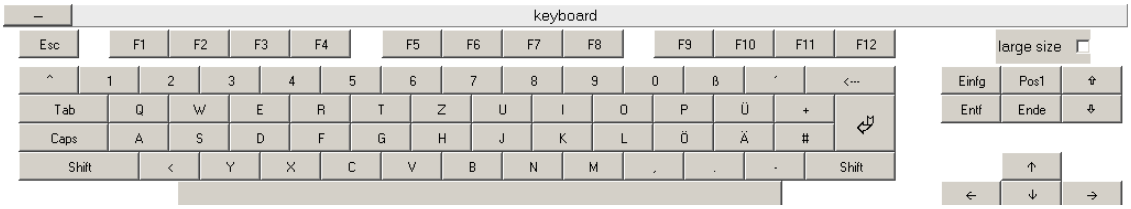
The software is constantly complemented and updated. For the newest update, please contact the company GAMPT mbH under info@gampt.de.
In the following documentation, the software BCView in the version number 3.4 is described. Other versions can show some deviations.

4.1. Overview

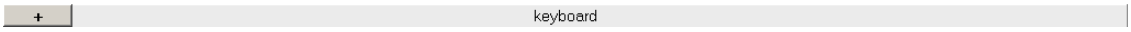
The software version BCView is a measuring, evaluating and documentation program for the Bubble Counter BC100 and BCC200. The program can be started in two fashions:

Without touch screen support (for BC100 or off-line evaluations):
For that purpose, you simply start the file **bcview.exe**. The program is controlled with the help of keyboard and mouse. At suitable places, the program asks the user for the settings of the measuring instrument.

With touch screen support (for BCC200)**:**
For that you start the file with an additional parameter: **bcview bcc**
(With the delivery of the BCC200 the software is installed accordingly. For the installation of updates a separate description is delivered.)
Now the program can be controlled with the help of the touch screen. In addition, a keyboard is faded into the lower screen edge in order to manage the input of information about patient and measurements. For changes of some pre-settings it is advisable to use a keyboard and/or mouse via the USB interface.



The **large size** key on the top right increases or reduces the faded in keyboard. If the keyboard is not needed it is possible to roll it up with [-] on the top left, a click on [+] unrolls it again.



Depending on the mode the program was started, some displays differ in the program. In the text the differences are pointed out.

The following chapters explain how the software is built up and which functions are available. These are in detail:

Main screen
- Overview about function and effect of the buttons on the main screen, as well as references to following chapters

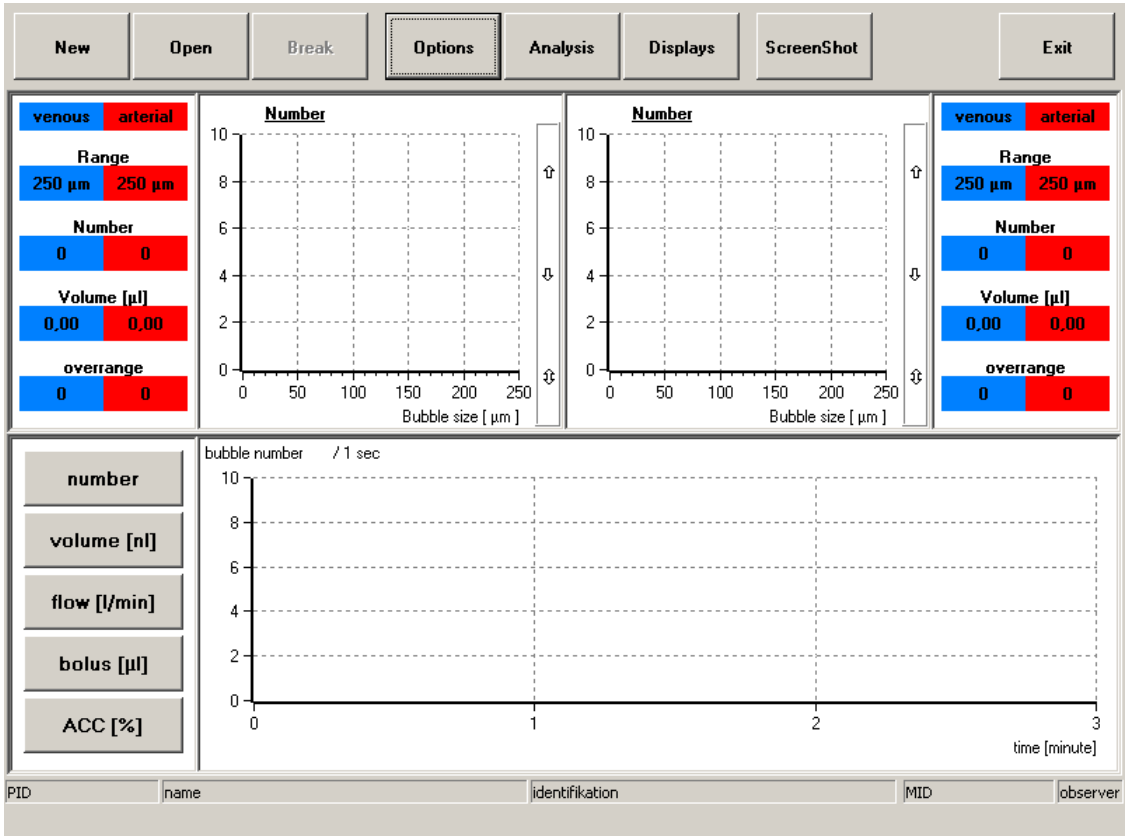
Database
- Structure and function of the database
- Creating and changing of patients data in the database
- Creating and selecting a measurement in the database

Measurements
- Measurement start and operation
- Measurement load and evaluate

Other windows
- Options
- Analysis
- Display

4.2. Main screen

After starting the program the main screen appears. New measurements can be started or already existing measurements in the database can be selected and evaluated.



With the help of the buttons in the upper edge diverse actions can be started or settings can be changed.

New A new measurement is started.
- Opens the "Patients selection" screen to input or select a patient (see database: Input Patient Data)
- Opens the "New measurement" screen and sets up a new measurement in the database (see database: new measurement)
- Starts the measurement (see measurement: starting and operation)

Open A stored measurement can be loaded.
- Opens the "Measurement Selection" screen (see database: measurement selection)
- Loads the selected measurement and displays it for evaluation (see measurement: load and evaluating)

Break Stops the measurement for a time.
- Only available during a measurement.
- The button changes to Continue, pressing again if the measurement should be continued.

ScreenShot Generates a screen dump and stores it as a jpg-picture.
- The name of the file is automatically generated.
- The file is stored in the export directory (see analysis: export: "change export path")

Exit Finishes the measuring program (the choice window opens for switching off the BCC200).

The other buttons open choice windows. Further actions or settings can be carried out with them.

Options Choice window for changing the pre-settings (see "Options"):

- Linguistic choice in English or in German
- Comments input of the predefined comments
- Parameter setting of the measuring parameters
- Port mode setting of the data transfer (only for BC100)
- About Info window about software version appears

Analysis Choice window to the documentation and continuing evaluation (see "Analysis"):

- Print Printer set up and print forms or protocols
- Export data export to ASCII or Excel
- TC-histogram temporal representation of the bubble distribution

Display Choice window for the turning on of additional function (see "Display")

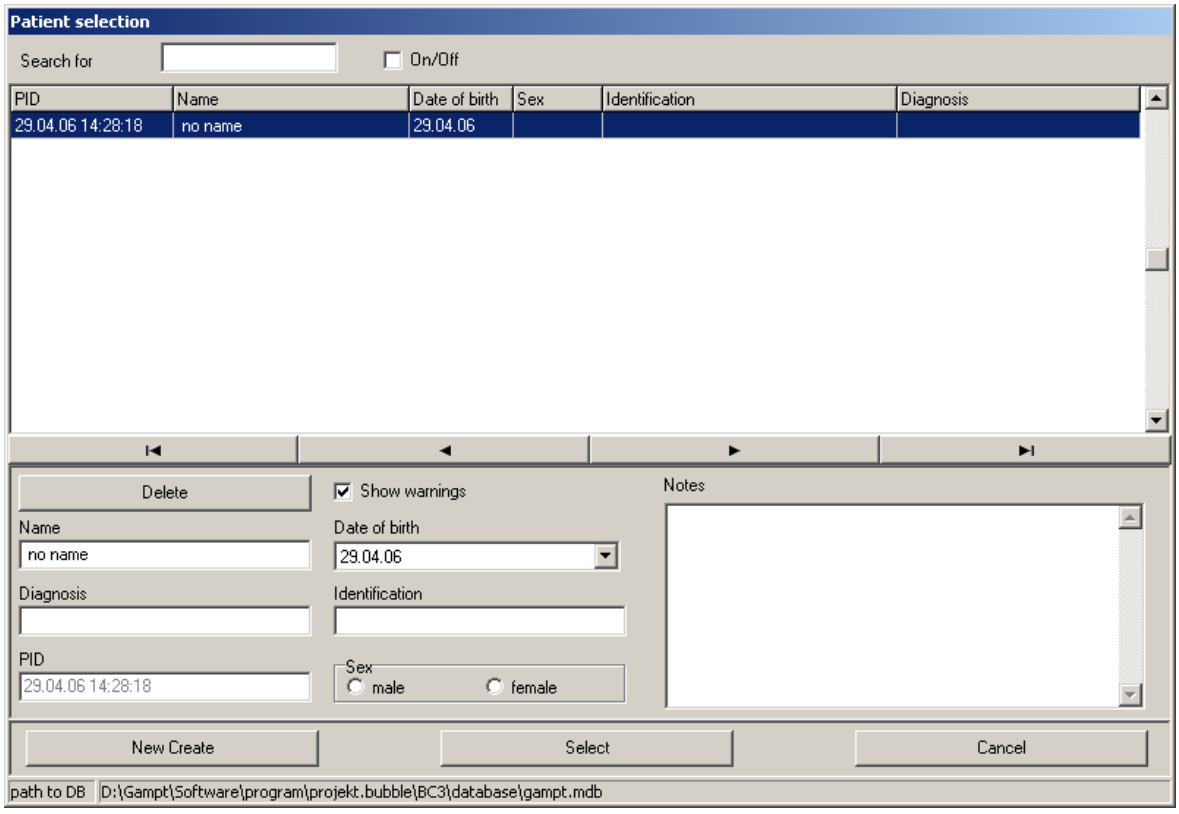
- Audio Control setting and control the volume of audio signal
- Cursor switch on/off of the evaluation cursors (see measurement: load and evaluate)

4.3. Software – Database

In this chapter the structure and functions of the database are explained. The database gives the user the possibility to manage the measurements fast and simply. The real measuring data are not stored in the database, but in external files. The connection between these external files and the information, which the user gives for the single measurements, is realized by the database. How the real measurements are carried out and are evaluated, is described in the chapter 3.4. “Measurements”.
The management within the database occurs in two levels. In the first level information about the patient (name, gender...) is put in. To each patient several measurements with their information like notes or other can assigned.

4.3.1. Input or Select Patient Data

Input and selection of patients data occurs in the window "Patient selection". This is opened if New is pressed in the main screen. (Alternatively one can open the patient's window also via choice to measurements, see 3.3.3.) Different descriptions can be given for every patient (name, birthday, gender, diagnosis etc.). The date and the time to which the patient was put into the database are automatically stored and serve internally for the identification (PID). For the measurements the identification occurs later in the same way (MID). With the help of these data the real measuring files are administered. The input masks in the lower part of the form serve to edit the patient selected in the upper part. Basically all editable fields of the database, the information of patient as well as of single measurements can be changed afterwards, too.



A standard patient with the name "no name" is generated by pressing the New Create button (if this patient already exists the program points out to it). The program jumps into the input field “Name”. Now the detailed data of the patient can be put in. Besides, it is to be noted that double names are not permitted, the program points to it. With the tabulator key one jumps to the next input field, one can select a certain field also directly with the mouse. As soon as one of the input fields is left, the program puts the corresponding data into the database and updates the text in the upper table.
If the input area in the lower part is left, the program checks whether the data are plausible and points out the user to discrepancies. However, this warning can be suppressed, when the hook beside the **Show warnings** button is deactivated. If the suitable text is confirmed, the normal run can be continued.

Already existing patients data can be changed or be completed. For that the patient is selected at first in the upper table, the corresponding data in the input field are indicated and can be corrected or be completed.

The **Search for** field is a filter. If the contents of this field are changed, only the patients whose names agree with the contents of the field are shown. Should this filter function be deactivated, either the given text can be deleted or the corresponding hook be deactivated.

The sorting within the table occurs always upwards. A pre-setting for the sorting are the IDs, i.e. the time, when a patient or a measurement were put in. The sort key can be changed by a single mouse click on the respective heading column of the table. (Sorting and filter apply analogously to the „Measurements selection“ window, see below)

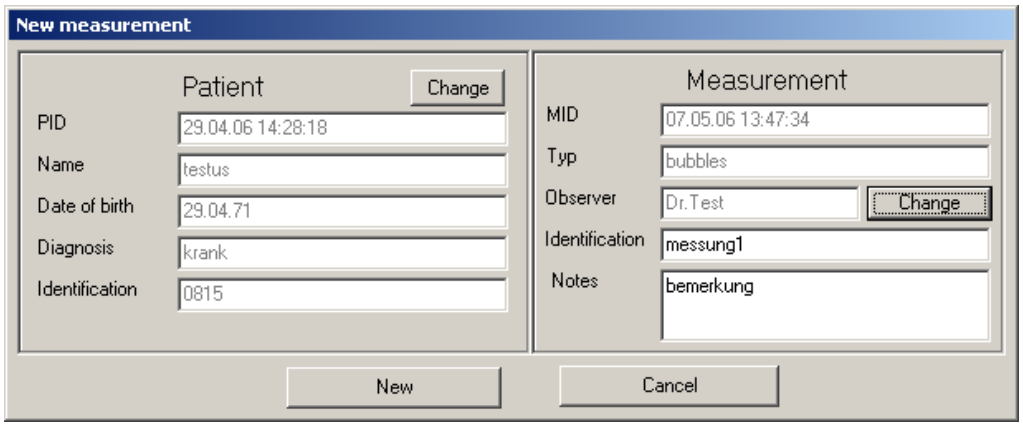
With Select the blue-marked patient becomes the actual patient.

With Delete the blue-marked patient is removed from the database.

- ***Attention!*** *With the deletion of a patient the information about the patient, the information about the measurements that belong to this patient as well as the matching measuring data are deleted. The program asks once again. If this is confirmed, the data will be removed.* ***Use it carefully!***

4.3.2. Database: New Measurement

If New was chosen in the main window, the "New measurement" window is opened automatically after the patients data input finished. In the left part the information about the before selected patient is shown, in the right part the information about the new measurement can be put in.



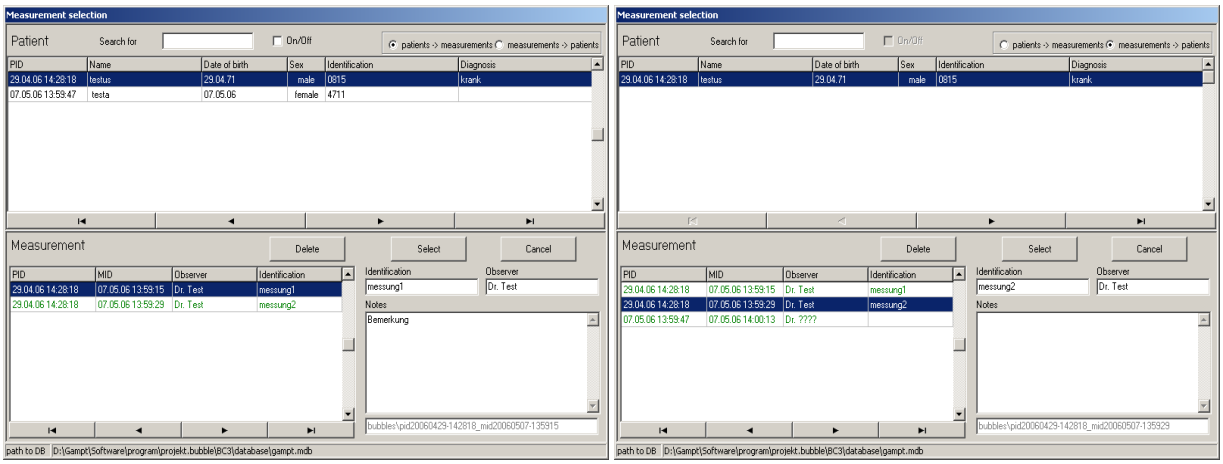
MID are date and time, at which the measurement is done, the measuring type serves for the description of the measurement. These data are given by the program and cannot be changed. Observers, identification and notes serve to describe the new measurement more exactly.

A click on New makes the database ready for a new measurement and the program jumps back to the measuring program (see chapter “Measurement start and operation”)

4.3.3. Database: Measurement Selection

The “Measurements selection “window serves to select a stored measurement. One reaches this, if Open is pressed in the main screen.

The patient's data stand in the upper part, in the lower part are the matching measurements, and on the right below the information about the selected measurement can be edited afterwards. A double click with the mouse in the upper table opens the patient selection window and allows if necessary the correction of the given patient's data. A double click in the lower table selects the chosen measurement and continues the program. This gives the same reaction as the click of the Select button (see below).



Important in this window are the choices **patients → measurements** or **measurements → patients** on the top right, they control the reaction of both tables together.

1. **patients → measurements**
   In the lower table only the measurements are indicated which belong to the patient who was selected in the upper table.
2. **measurements → patients**
   In the lower table all stored measurements are indicated, in the upper table appears in each case the matching patient.

With that the user has the possibility of either patient-oriented data selection, or to sort them, e.g., according to the given identification. The **Search for** field refers to the name and is only available, if **patients → measurements** was selected.

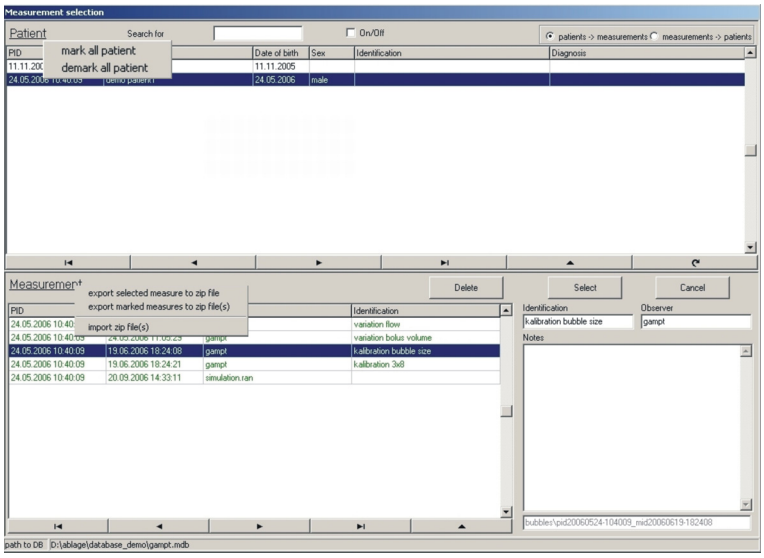
With the Delete button the actually chosen measurement of the lower table as well as the matching measuring data are deleted, the patient's data and the other measurements are preserved.

With Select the information of the selected measurement is passed on to the program and this continues in its run.

4.3.4. Database: Export / Import

To evaluate a measurement at an other PC the data has to export to this. It is also possible to use the export function to archive or backup the data. The program collect all relevant data from the database and the stored data files and compress these to a zip-file. For each measurement one zip file will be created. These zip files then can be copied to an other computer and imported there.
The data Export will be done in the window „Measurement selection“. Thereto one or more measurements can be selected.

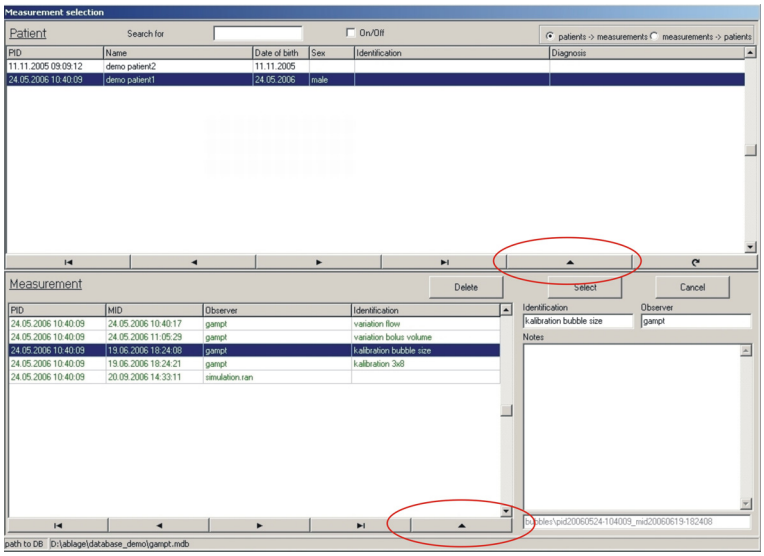
Export single measurement:



To export a single measurement select this in the list in the bottom window part, the measurement will be marked blue. Now click with the mouse to the label “Measurement” over the list of the measurements. Therefore a pop up menu appears, select there the line “export selected measure to zip file” (see figure, bottom part).
In the next step the program ask for path and filename to save. It suggest a name generated from the patient-ID (PID) and measurement-ID (MID). For export single measurements the filename can be changed.
The so saved file can be imported later into an other database.

Export several measurements:

To export more than one measurement, these has to be marked first. To mark a measure, select it and then press the space button of the keyboard. To demark press space button again. A marked measure will shown with bold letters, all others with normal letters. Alternatively to the space button the triangle symbol in the icon list below the list can be used.



How to see in the figure the triangle symbol exists also below the patient list. Selecting this the patient will be marked. The meaning of patient marked is, that all measurements of this patient will be marked. So it is not necessary to mark all the measurements. Demark a patient will demark all his measurements.
To export the complete database all patients can marked in one step. For this click the label “Patient” above the patient list and select the popup menu line “mark all patients” (see previous figure). But keep in mind that marking all patients especially for large database can take some time.

Are the measurements or patients marked they can be exported. For this click with mouse to the label “Measurement “ and select the popup menu line “export marked measurements to zip files”. The export will be done into the export directory of the program (see also chapter “Analysis/Export”). If the directory is not yet defined it can be done now. The program do not ask for the filename of each measurement, it will be generates automatically by using PID and MID. After successful export in the directory should be so many new zip files how measurements were be marked.

Import measurements:

To import measurements click to the label „Measurement“ above the measure list and select “import zip file(s)”. The program ask, where the files are and which should be imported. It is possible to select more than one zip file. Are the zip files selected and confirmed the program import the corresponding data into the database.

- ***Attention!*** *Select only zip files to import, which are exported with this program before. The zip files have an internal structure which is needed for successful import!*

4.4. Measurements

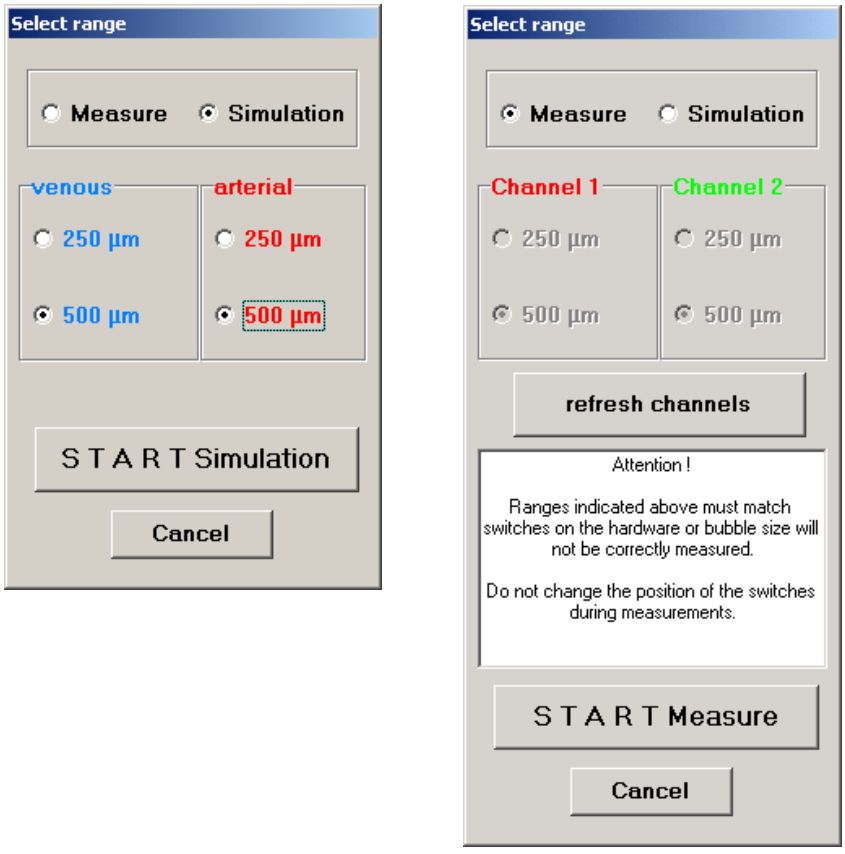
4.4.1. Measurement: Start and Operation

To start a measurement [New] is chosen in the main screen. After the information about the patient and the measurement were given into the database, the program still needs the information in which size range should be measured. For that the "Select range" window appears. Here one defines up to which size bubbles should be classed during the measurement.

If the program was started with touch screen support (BCC200) the left window appears, with the BC100 the right window is shown. Should no device be connected or be recognized by the program, it automatically switched to **Simulation**.

With the BC100 the channel choice is done with switches at the front panel of the device. On the screen the choice then is shown. With [refresh channels] the display can be updated.

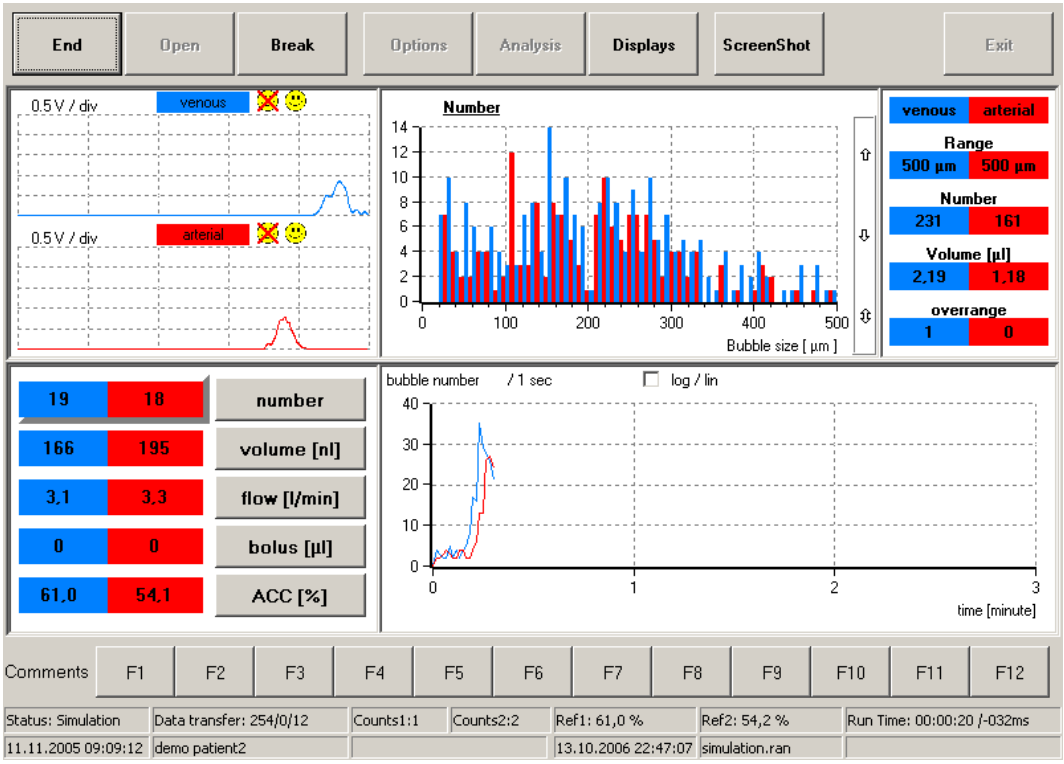
With the BCC200 the setting of the channels is carried out on the screen.



[Cancel] breaks off putting to use the measurement, the program returns to the main screen.

With [Start] the real measurement is started.

After a measurement was started the measuring screen appears:



On the measuring screen there are three displays:

a) On the top left: actual measuring signals
b) On the top right: histogram with accumulating values
c) Below: time course with actual values

a) On the top left the actual measuring signals of both channels are displayed. If bubbles are in the ultrasonic field at the moment of the measuring, these are registered as peaks in the measuring signal. The height of the peak is a measure of the size of the bubble. Their position on the x-axis indicates the time of their appearance. If a peak exceeds a certain height, it is registered as a bubble and is stored with size and time in the data file. Both smilies are status messages, the first stands for the data transfer, the second for the acoustic properties of the system (see also ACC).

b) On the top right a histogram is shown, with all bubbles counted so far. The histogram channels correspond to the bubble size in µm. Which range (250 µm or 500 µm) is indicated depends on the choice while starting the measurement (see select range). The colour marked values to the right show the total values registered at the actual time. In the picture histogram so far 231 bubbles with a total volume of 2,19 µl were registered in the venous channel and 161 bubbles with 1,18 µl total volume in the arterial. Should a bubble appear which bigger than the chosen measuring area (here, e.g., 500 µm), the program cannot classify it. Such a bubble is valued as “over range” and so it is counted. The total number of all bubbles is the sum of the bubbles inside and overrange (number + overrange) . For the volume calculation of such “over range” bubbles the maximum value of the measuring range is assumed (here 500 µm) and this is added to the total volume (that did happen one time in channel 1).

Above the y-axis in the histogram stands the underlined unity. Ordinarily this is the number of the bubbles in the histogram channels. With a mouse click on this unit it is possible to switch from number to volume. Background is the following consideration: many small bubbles have not necessarily a bigger volume than few large bubbles. The volume of 20 bubbles with a diameter of 10 µm amounts to 10472 µm³, the volume of 1 bubble with diameter of 30 µm amounts to 14137 µm³. With switching the unit the user has the possibility to judge also the volume distribution of the bubbles in the histogram.

c) In the lower part the time course of the measurement is shown. Here the number of the appearing bubbles in a time interval of 1 sec is added up and is shown on the y-axis (alternatively linearly or logarithmically), with very long measurements (about several hours) the time interval increases to 5, 10 sec etc.. The colour marked values on the left beside of the diagram are 5 different values of the last measured interval. These are:

Bubble number:
Is the total number of all bubbles that were counted in the last time interval, the respective size of the single bubbles is used for the histogram calculation.

Bubble volume [µl]:
Is the volume of all bubbles of the last time interval. The volume is determined with the help of the diameter of the single bubbles. In the histogram one can switch to volume representation.

Flow rate [l/min]:
The mean value of the speeds of the single bubbles is determined and a flow speed is calculated with the help of the tube cross section. It is to be noted that the middle bubble speed must not necessarily agree with the middle speed of the flowing medium, because of streaming profiles and local bubble distribution.

- ***This value does not substitute a clinical flow meter !***

Bolus volume [µl]:
If the bubbles are too big or there is too much air in the measuring system, the Bubble Counter cannot quantify the bubbles any more individually. Therefore, with a bigger amount of air in the system the bolus volume is determined. This is not calculated any more with the help of single bubbles, but illustrates the total volume of air in the measuring system.

- ***Bubble- and Bolus volume both measure the same air . These are different procedures applied to the same air volume.***
- ***The both values cannot summarize together, in case of doubt use the higher value.***

ACC - Acoustic Coupling Control [%]:
The size of the measuring signals depends not only on the bubble size, the real measuring signal, but also on the acoustic properties of the measuring system. That means the coupling between probe and tube and among others the attenuation of sound in the tube or in the medium. The ACC represents a measure of these qualities. It is controlled during the measurement constantly and is used for the correction of the measuring signals. If these qualities change during the measurement, e.g., by warming up the medium or the tube material, this is registered by the measuring system and is corrected accordingly. If the value of the ACC is too low, the height of the measuring signals is insufficient for a quantitative evaluation (this case is indicated by the second smiley in the diagram of the measuring signals)

Which of the five signals (number, volume etc.) is plotted in the time course, can be chosen by the corresponding button.

Comments:
During the measurement comment texts can be stored at any times. (e.g., to document the addition of additives). These comments are shown later in the time course accordingly. There is the possibility to store up to 12 different predefined standard comments. These predefined comments are stored with the functional keys F1 to F12 or by a click on the suitable button in the lower screen edge. The text of these 12 comments must be given before the measurement. For the input of these texts see chapter 3.5.2.1. “Input comments”

Only for BC100: If the program was started without touch screen support, an additional field editor is available. To this eligible texts can be given during the measurement freely. Pressing the ENTER key this texts are taken over as comments in the measurement.

If the Break button is pressed, the program switches off the measurement temporarily. The Break item changes to Continue. If this button is pressed again, the program continues the measurement.

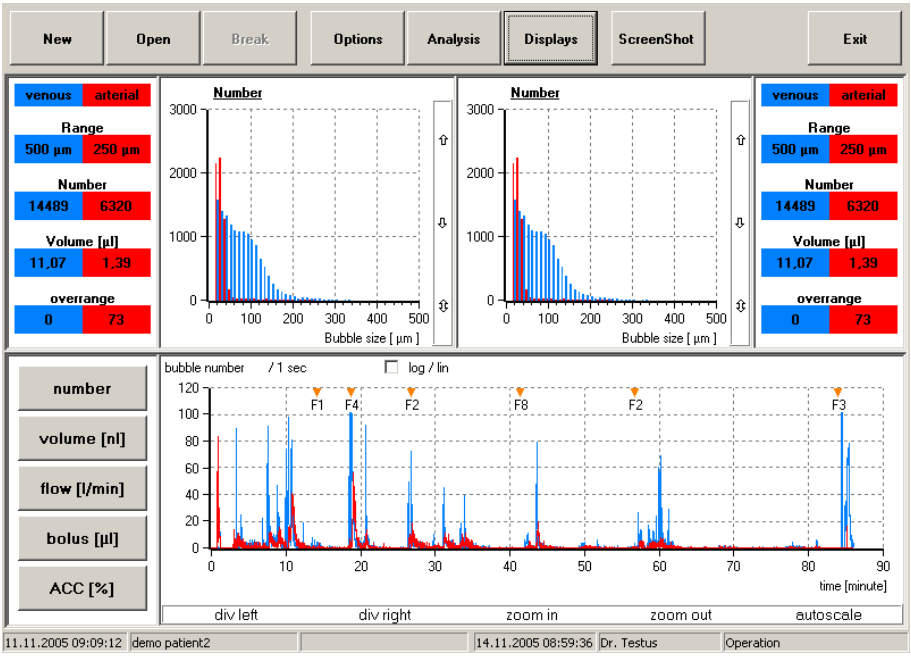
ScreenShot stores the actual screen as a picture in the export list.

Display leads to the “Audio Control“ window to control the volume of the loudspeakers during the measurement.

A measurement is concluded with End. The program asks whether the measurement should be stored. If not, all data are deleted and the program returns to the main screen. If the question is answered with yes, the data are stored and this is confirmed. The program likewise returns to the main screen and loads there automatically the last measurement.

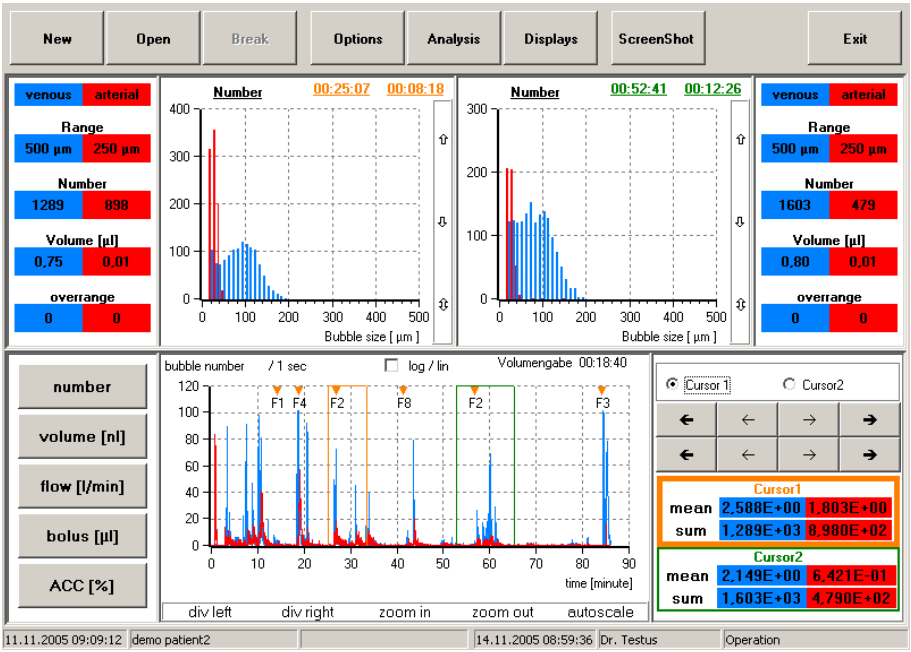
4.4.2. Measurement: Load and Evaluate

If a measurement was finished or a stored measurement from the database was selected to the main screen with the help of the Open button, the display is like the following.



The layout of the window is similarly to that during the measurement. Now there are two histograms in the upper part, in the lower part is again the time course. After the store of the measurement the whole time area of the measurement is shown in the lower window for the moment. Both histograms contain the information about the whole measurement, both histograms are identical directly after loading.

With the help of the buttons in the lower edge of the time window, you can zoom in or zoom out in the time course. This serves to have a look more in detail at specific time periods, especially with long measurements. Zooming within the time window has no influence on the representation of the histograms.



To get information about the size distribution of a certain time interval, one can calculate histograms for this interval. Via the Display button one chooses the Cursor button. On the right below appears a field by which one can control two cursors in the time window. With the help of the arrows you can control the cursors, namely with the upper row the position and with the lower row the width of the cursors. Depending on how the cursors are put the plot of the histograms are changed. Cursor 1 creates the left histogram with the blue time message above, Cursor 2 creates the right histogram with the pink message. Now the histograms are calculated only for the selected time intervals (i.e. the cursor width). The precise information about the selected time intervals is shown in the corresponding histograms as coloured underlined times on top. The first number is the start time of the time interval and the second the duration. With that, it is possible to compare the size distributions of two time intervals with each other.

A mouse click on the underlined times message above the histogram switches off the respective cursor. The histogram indicates again the result for the whole measuring course.

With the help of the cursors you can determine also the average and sum of a time interval. These are calculated from the values shown in the time course and are indicated below the arrows for cursor control. Which value is indicated there, depends on the actual signal, which is shown in the time course.

- *The interpretation of these values lies in the responsibility of the user. Thus it is not reasonable to calculate the sum of 10 min flow speed, while the average value absolutely makes sense.*

If comments are given during the measurement, they are shown as blue triangles in the time course on the x-axis. Because the whole comment text cannot be written to the axis, only the number of the suitable functional button is indicated there. Here another meaning is related to the blue cursor. Depending on where the left edge of the blue cursor stands the last given comment text and the time of the input is indicated in the time window on the top right.

The cursors are always preserved on the screen, even if their control and display of the average and sum is faded out by pressing the Cursor button in the **Display** window. The position and width of the cursor can also be changed directly with mouse or keyboard:

Blue rectangle: histogram on the left

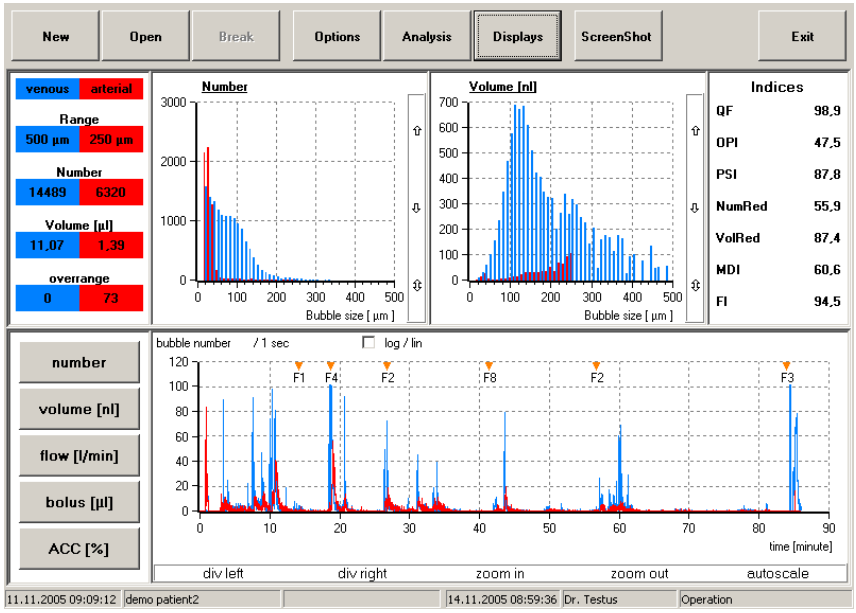
With mouse	
left edge of the bar	Mouse click left key
right edge of the bar	CTRL + mouse click left key or click and pull
With keyboard:	
+ 1 sec shift (to the right)	POS1
- 1 sec shift (to the left)	END
+10 sec shift (to the right)	SHIFT + POS1
- 10 sec shift (to the left)	SHIFT + END
+ 1 sec wider	CTRL + POS1
- 1 sec narrower	CTRL + END

Pink rectangle: histogram on the right

With mouse	
left edge of the bar	Mouse click right key
right edge of the bar	CTRL + mouse click right key or click and pull
With keyboard:	
+ 1 sec shift (to the right)	Page up
- 1 sec shift (to the left)	Page down
+10 sec shift (to the right)	SHIFT + Page up
- 10 sec shift (to the left)	SHIFT + Page down
+ 1 sec wider	CTRL + Page up
- 1 sec narrower	CTRL + Page down

4.4.3. Indices

To be able to judge a measurement or the effect of a single component, we created some indices. E.g., the job is to compare different filter or filter systems. For this we have to compare the input (measured signal before the filter) with the output (measured signal behind the filter). The indices should help to do this. They appears when the histograms switch to the volume display by mouse click on the title of the y-axis (Numbers or back Volume) See right histogram in the picture.



The shown Indices values are calculated from the currently shown histogram. So when there was selected a time section for the histogram, the indices are valid only for this time section. Pay attention to this comparing different measurements.
For the calculation most of these indices we have to compare input and output of the system. So the correct assignment of the probes is very important for the calculation. Preadjustment is Channel 1 = venous as input and Channel 2 = arterial as output. A wrong assignment can gives absurdly values.

QF (Quality Factor):

Before we start a measurement we have to select the range. Bubbles which are larger the range are judged as "over ranged". There diameter and derived from this the volume are assumed with the maximum value of the range. Because of this especially for the volume calculation there will be inaccuracy. More overranges gives more inaccuracy for the calculated volume. The quality factor is a measure for the number of over ranges. If there were no overranges the quality factor will be 100%, it decrease with the number of overranges. For this both channels are combined.

OPI (Operation Index) and PSI (Patient Safety Index):

These both values are measures for the volumes at the arterial and venous side of the system. We did the following thought: When there goes no air volume from the system to the patient, there will be no act of damaging at the patient. The patient safety is given. When there are air bubbles in the arterial line the probability of damaging the patient increase. Even more air bubbles decrease the patient safety.

- *The terms damage and patient safety here only used as a result of air bubbles, other risks don't consider here. Furthermore pay attention we assume the hypothesis that the probability of a damage increase in a cumulative manner with the air volume during the operation. The size of the bubbles or their concentration will not consider to date.*

Starting from this point we define the Patient Safety Index. When there is no air volume in the arterial line the probability of damaging is zero, the PSI is 100%. Even more air volume decrease the index during the operation. Analogously to the PSI at the arterial side of the system we define the Operation Index at the venous side. The PSI describe how many air comes from the system to the patient. The OPI shows how many air comes from the patient or from the operation area into the extra corporal circulation. With it the air input of different measurements or operations can compared. The value of the OPI will mostly be smaller than the PSI, because the HLM will move out air from the circulation.

Both indices are scaled in the same way, pay attention the progression is not linear. As clue for the indices some values:

Index	99 %	98 %	80 %	50 %	40 %	20 %	10 %
Volume	0,1 µl	0,2 µl	2,5 µl	10 µl	15 µl	40 µl	90 µl

- *The shown indices OPI and PSI are suggestion for an easy way of characterization a measurement or an operation. We cannot judge about the clinical relevance of these values.*

The following indices have more technical character. They should help to compare the mode of work and action of different systems or components.

NumRed (reduction of bubble number):
To compare different components i.e. filters, we examine for how many percent the bubble number decrease. In the picture above the input was 14489 bubbles, the output was 6320 + 73 = 6393 bubbles. So the bubble number was decreased by 55.8%. Would be the reduction by 100% all bubbles would be eliminated. There can also be the case, that more bubbles are behind than before the filter. This can be when in the filter large bubble breaking up into small particles, There is a volume reduction but the number of bubbles would increase. In this case the NumRed-value would be negative.

VolRed (reduction of bubble volume):
The calculation of the VolRed is analogously to the NumRed. In the example the input was 11.07 µl and the output 1.39µl, so there was a reduction by 87.4 %. That the volume reduction gives negative values should never happens. This can only take place when the assignment of input and output was mixed up or when there was air in the system, when starting the operation. Else the meaning would be there is an additional air input into the system. Possibility could be the add of drugs, Kardioplegie or something like that. But this of course is to avoid.

MDI (Mean Diameter Index)
When there come bubbles into the filter, so the large bubbles will be eliminated. Only smaller bubbles can pass the filter. The size of these bubbles depends from the filter system. When we calculate the mean diameter of all bubbles before and behind the filter, the mean diameter behind should be smaller than before, because behind the filter the large bubbles absence. The Mean Diameter Index shows by how many percent the mean diameter was decreased.

FI (Filter Index)
We herein before mentioned that the bubble number can increase in the filter, nevertheless the volume will decrease in the same case. So we have in calculation two directions for the indices number and volume reduction. The Filter Index FI combine both indices and should help to get a statement about the mode of action and the total effect of the filter.

- ***If there is a Bolus event, then the Bubble- and Bolus volumes are compared and the higher value will be used. This has an impact to all indices depending from a volume.***

Mathematical definitions:

$$QF\,1 = \frac{bubble\ number\ without\ overranges}{bubble\ number\ without\ overranges\ + number\ of\ overranges}\langle input\rangle$$

$$QF\,2 = \frac{bubble\ number\ without\ overranges}{bubble\ number\ without\ overranges\ + number\ of\ overranges}\langle output\rangle$$

Quality Factor: $QF = QF1 * QF2 * 100$

Operation Index: $OPI = \frac{1}{1 + Volume\langle input\rangle} * 100$

Patient Safety Index: $PSI = \frac{1}{1 + Volume\langle output\rangle} * 100$

D_i : diameter of the i-ten histogram channel
N_i : bubble number with the diameter D_i, (number is with overranges)
V_i: volume of a bubble with a diameter D_i

Bubble Number Reduction: $Num\,\mathrm{Re}\,d = \left(1 - \frac{\sum N_i\langle output\rangle}{\sum N_i\langle input\rangle}\right) * 100$

Bubble Volume Reduction: $Vol\,\mathrm{Re}\,d = \left(1 - \frac{\sum N_i * V_i\langle output\rangle}{\sum N_i * V_i\langle input\rangle}\right) * 100$

Mean Diameter : $MD = \frac{\sum N_i * D_i}{\sum N_i}$

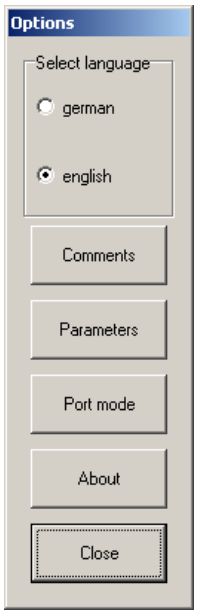
Mean Diameter Index: $MDI = \left(1 - \frac{MD\langle output\rangle}{MD\langle input\rangle}\right) * 100$

Filter index FI $FI = \left(1 - \frac{\sum N_i\langle output\rangle}{\sum N_i\langle input\rangle} * \frac{\sum N_i * V_i\langle output\rangle}{\sum N_i * V_i\langle input\rangle}\right) * 100$

4.5. Other windows

In order to carry out quickly the necessary commands also with the touch screen, further menu boards were abandoned. Because of the limited place on the main screen, the more seldom required commands were assigned to subordinated choice windows. These can be selected in the main window Options, Analysis and Display. Besides, options serves to fix pre-settings, analysis is used for the documentation and evaluation and display is used for additional functions. In this chapter the contents of the different choice windows are explained.

4.5.1. Options



If the Options button is pressed in the main window, a choice window opens, by which different pre-settings of the program can be carried out. In the upper part the language can be chosen, as a result the names of the buttons change. (On error or instructions messages which are not generated by the program this language button has no influence. All the names of the signals in the histograms as well as in the time course remain in English.)

Comments leads to the input of the predefined comment texts

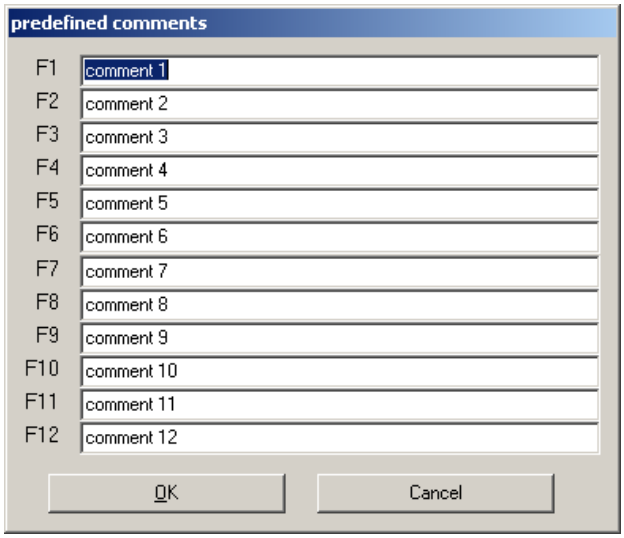
Parameters leads to the input of the probe parameters and measuring parameters

Port mode is available only for BC100 and leads to the setting of the data transfer

About shows an info window with the version number of the software and contact information

Close closes the window and returns to the main screen

4.5.1.1. Input Comments



During the measurement predefined comments can be stored at any times. (see also chapter Measurement starting and operation) The text of these comments must be given into this window before the measurement. The predefined comments are still available by the next starting of the program.

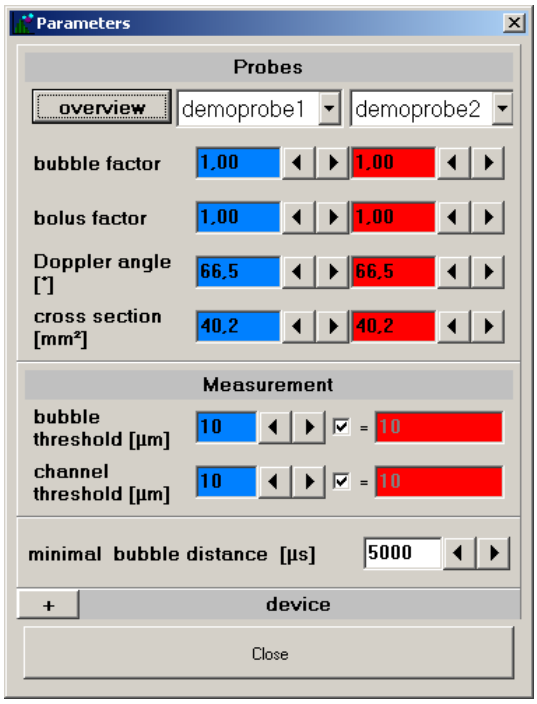
(With some Windows versions the program is stopped with F10. In this case this button should not be used for comments. If no text is given into the corresponding field, this comment is deactivated during the measurement)

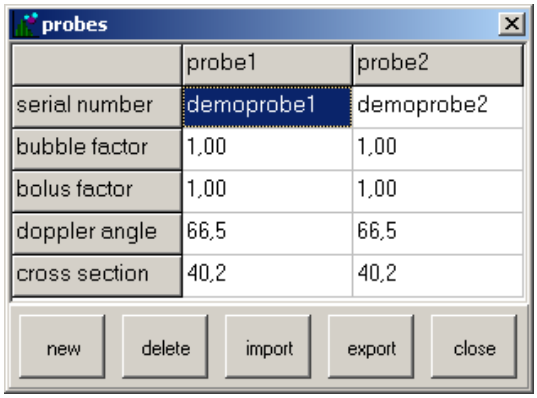
4.5.1.2. Parameters

- ***Attention!*** *Changes in this form have direct influence on the measuring values, wrong or senseless inputs can lead to wrong measuring values*

We have improved the possibilities to measure with the bubble counters. Now beside the known 3/8" probes there are also probes for ½" and ¼" tubes available. To work with this we have to changed the software. In the software BCView since version 3.3 we calculate the bubble size using calibration factors. Each probe has an own calibration factors. These factors have to be input into the program before starting a measurement. When there are no or wrong calibration factor in the software, the estimated bubble size will be not correct. To each device and probe a calibration protocol is delivered. In this you will find the factors. (For the BCC200 the factors will be input at the installation)

Parameter calibration factors:





To feed in the calibration values, please start the program. With Options/Parameter you come to the input window.
The shown values in the probes section are the calibration factors. They variety depending device and selected probes. The first collared values are valid for Channel 1 (venous), second collared values valid for Channel 2 (arterial). It is very important to keep the right assignment between the probes, the connection socket and the selected values.

In the first line of the Parameter window it is possible to select with which probe you want to work. Changing this makes only sense, when there are more than two probes available.

- ***Important!*** *When you change the probes at the device, you have to tell it here to the program before starting the next measurement. The program works always with the calibration values selected here.*

The next four lines contain the different calibration factors. The bubble factors is needed to estimate the bubble size, bolus factor is for calculation larger air volumes. Doppler angle and cross section are needed to calculate the speed and flow rate of the stream. (for more information see also chapter Measurement: start and operation). The meanings of bubble and channel threshold are explained in Parameter Measurement below.

With "overview" you come to an other window, where all probes the program knows are shown. Here you can also edit the name and values of the probes, but normally it's not necessary. With import it's possible to give in new probes, but for this a special file with data is needed. (when needed, we will send it).

Parameter Measurement:

The values under Measurement in the parameters window determine the lower limit of a measurement. The smallest measurable bubble size depends at first on the used hardware and is given in the chapter technical data under measuring resolution.
However, under certain circumstances it can be sensible not to measure up to the ultimate possible resolution. This is, e.g., the case if the noise or disturbances are too big or if small bubbles are indicated due to pumping rumble, which do not exist at all. The values of bubble threshold and of channel threshold give the user the possibility to define an appropriate low limit.

The meaning is the following:
bubble threshold minimally registered bubble size
channel threshold minimally counted bubble size

If a bubble is bigger than the bubble threshold, it is registered as a bubble, it is stored and further evaluated. If the bubble is too small, it is ignored and the program continues with the next bubble.
In the next step, it is checked whether this registered bubble is bigger than the channel threshold. If this is the case, it is classified, arranged in the respective histogram channel and included accordingly in the time course. If the bubble is too small, it is ignored for further evaluation.
Both threshold values act as low filter limits and the bubble threshold decides whether the bubble is stored and is evaluated afterwards, the channel threshold decides whether it is evaluated and indicated. The higher the bubble threshold is, the fewer small bubbles are registered and stored, the corresponding data files become smaller and the evaluation runs faster. Disadvantageous is that once rejected bubbles are lost for later evaluation. On the other hand, the channel threshold acts only on the actually indicated data, it can be varied, e.g., during the evaluation. Besides, it is to be noted that a channel threshold smaller than the bubble threshold is senseless.

- *The values here are valid for the 250 µm range. In the 500 µm range the treshold increase two times. Pay attentiont the default values are 10 µm. So in the 500 µm range no bubbles smallerthan 20 µm will be registrated.*

minimal bubble distance:

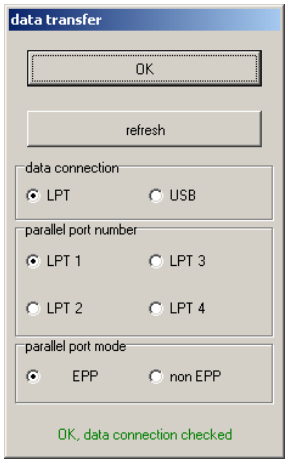
For the Bubble Counter a limitation value is the bubble concentration. When the bubble number per second is to high or when two bubbles come closed together then there are multiple bubbles in the sensor volume at the same time. Normally when there comes a single bubble we get a single peak as signal. When there are to many bubbles in the flow or two bubbles come touched together into the sensor area we get not only single peak , it gives a double peak or a peak with a shoulder. When the distance between the two peaks is to small only one peak will be counted, the smaller one will be ignored. Criterion for this is the minimal bubble distance in µs. Is the time between two peaks is smaller than the minimal bubble distance, only the larger one will be counted.
The default value is 5000µs. So it would be possible to count 200 bubbles per second (=1sec/5000µs =200), but this is a theoretical value. For this it would be necessary, that the distances for all these bubbles are exactly 5000µs. Normally for real measure it would been never reached.
With the parameter minimal bubble distance the customer can adapt how many bubbles could counted. When the value is set to high, multiple bubbles are counted as one large bubble, thereby less bubbles will overall counted and the mean diameter will shift to a higher value. Is the parameter set to smaller value, more smaller bubbles will be estimated.

Parameter device:

Under the line “device” the gain factor and reference factor will be found. These will be used to adapt special hardware configurations. For normal configuration these values have to be 1.00. Changing these values should be done only after consulting GAMPT.

4.5.1.3. Port mode

- *This window is not available for the BCC200 ! The corresponding settings are carried out by the installation.*
- *The window serves to install the communication of the measuring instrument BC100 with the PC or laptop. If wrong values are put down here, the data transfer between PC and measuring instrument does not function properly.*



The data transfer between measuring instrument and PC occurs via the parallel interface. If several interfaces exist, the program has to be informed here to which measuring instrument it is connected (pre-setting is LPT 1).
To reach a high transfer rate the program tries to do the data transfer in the EPP mode. (Possibly this must be activated in BIOS of the computer). If the computer does not support the EPP-mode, one can switch here to non EPP.

It is also possible to use an optional USB-adapter. Then use the data connection USB.

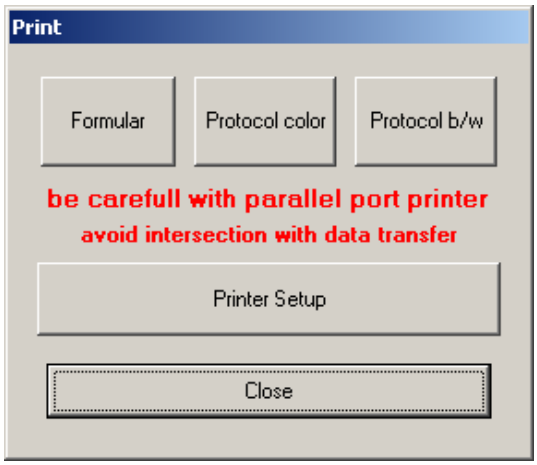
4.5.2. Analysis

When the data were stored after a measurement, they can be printed out for documentation or be exported to further evaluations. At first step, the measurement is loaded in the main screen and is displayed. Then with the help of the Analysis button you can decide what should happen with the data:

Print	prints protocols or forms
Export	data export to ASCII or Excel
TC-Histograms	time course of the bubble distribution
Close	closes the window and returns to the main screen.

4.5.2.1. Print

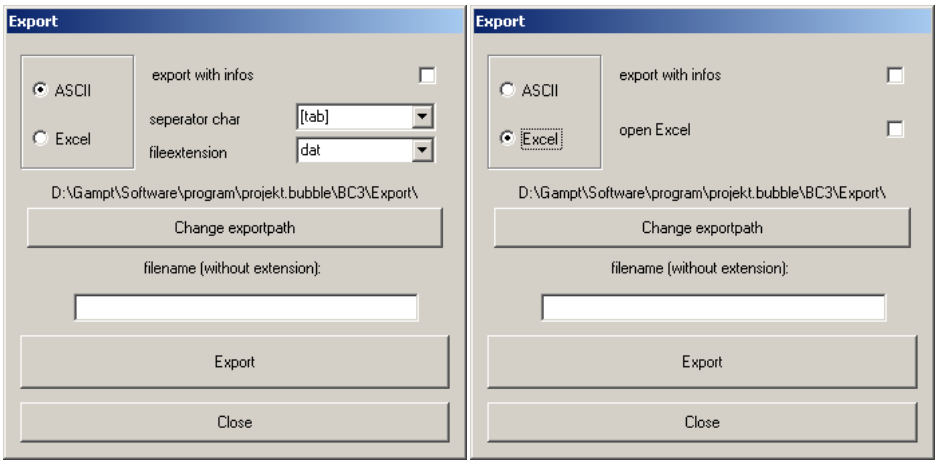
To be able to print the data, a printer must be installed at first. If still no printer is installed in Windows, one can accomplish this here by Printer Setup.



- *Since the data communication of the measuring instrument works via the parallel interface of the computer, attention must be paid to the choice of the printer in order to avoid interferences.*

With the Formular button the actually indicated main screen is sent to the printer. With the Protocol color button a coloured protocol is build, with the Protocol b/w button a black/white protocol is build, in which the histograms and the different time courses are shown. Afterwards this can be printed.

4.5.2.2. Export



Two formats are available for the export, firstly the export into text files (ASCII, left picture) or directly to Excel (right picture). Condition for the Excel export is that Excel is installed on the computer. In both cases the files are stored in the export directory, with the help of the Change export path button the directory can be changed.

- *The pictures, which are generated by* ScreenShot *on the main screen, are likewise put into this directory.*

In **filename** you have to put in the name where the file should be saved. Always three files (ASCII) or 3 data sheets (Excel) are exported, the time course as well as two histograms. All that is exported what is indicated in the main screen. If with the help of the cursor certain areas were selected and the histograms of these areas were calculated, these histograms are exported. If no area was chosen, both exported histograms contain the data for the completely measuring period.

With **export with info** information about the selected patient or the measurement are also exported beside the real measuring data.

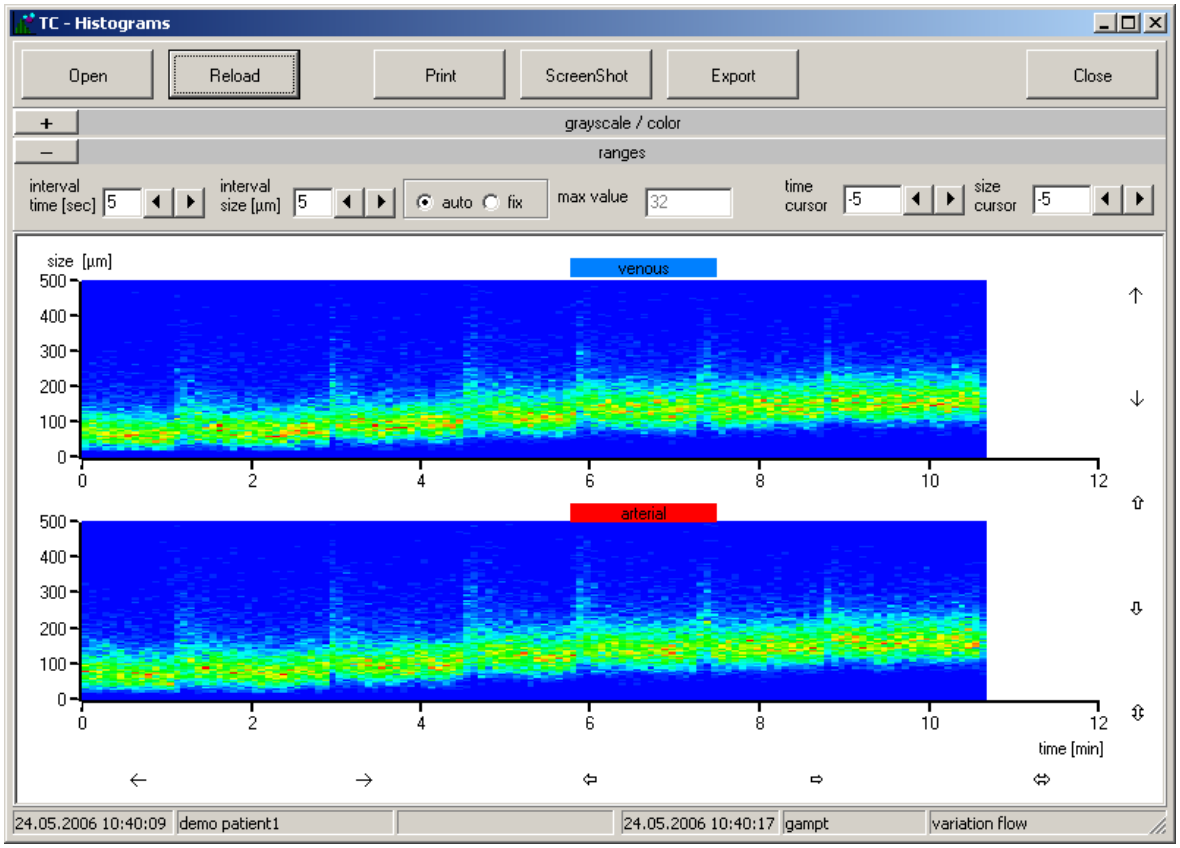
For the ASCII export the program uses the sign that is given in **separator char** as a separator between two column values in the export file. With **file extension** a file extension can be given. There exist in each case three defaults, these can be, however, must not be used.

For the Excel export it is not necessary to give these values. If the option **open Excel** is activated, the program will open directly the corresponding file in Excel.

- *To be able to continue in the run, the program will close Excel. Should changes have been carried out in the Excel data, these should be stored before continuing, the program points accordingly to it.*

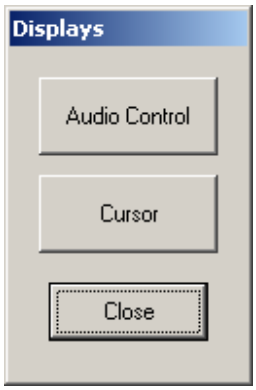
4.5.2.3. TC-Histograms

Usually the sum of the bubbles over a time interval is added and this sum is shown as time course in the main window. The normal histograms indicate the bubble distribution over a selected period of time.
In the TC-histogram window the size distribution of the bubbles can be shown in the time course. The upper picture shows the distribution for Channel 1, the lower for Channel 2. On the x-axis the time is given, on the Y-axis the bubble diameter is shown. The number of the bubbles of a certain size measured in a time interval is shown colour-coded. The more bubbles appeared in this time interval, the redder is the area in the picture.



With the help of the values in the segments grayscale/colour and ranges the representation can be adapted. The **interval time** value fixes over how many seconds the sum should be taken, it determines the width of a pixel on the x-axis. The **interval size** value describes how many channels of a histogram are summarized, it determines the height of the pixel at the y-axis. The **max value** gives the number, which is assigned to the highest colour value (red). If the choice **fix** is selected, the user fixes this value. With that, it is possible to compare different measurements in the same colour scaling. If the choice **auto** is selected, the program places the max value automatically to the highest value in the actual measurement. It is to be noted that changes of the interval values respond only with the loading of a measurement. One loads a measurement by Open. This works like in the main window. The Reload button serves to update the display after changes in the range area. The selected measurement is loaded once again, now the pictures are calculated with the new values from the range area. With the help of the settings below **grayscale / color** the pictures can be adapted even further. Gray or rainbow fixes whether the pictures are grayscale or color coded. With level/width the contrast of the pictures can be changed. (This analogously functions of the window technology (level / width) as it is applied, e.g., with computer tomography-pictures. Here the values are indicated in percent, 100 % corresponds to the value given in **max value**).

4.5.3. Display



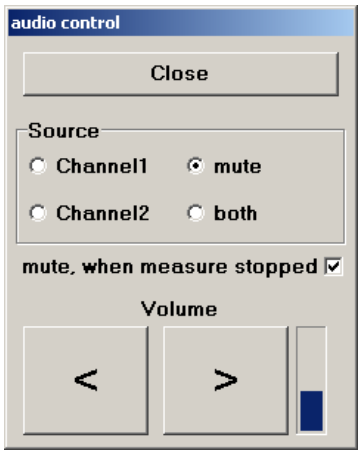
The display window serves to switch on/off additional topics.

Audio Control opens the window for Audio Control

Cursor switches on/off the control of the evaluation cursor on the main screen

Close closes the window and returns to the main screen.

4.5.3.1. Audio Control

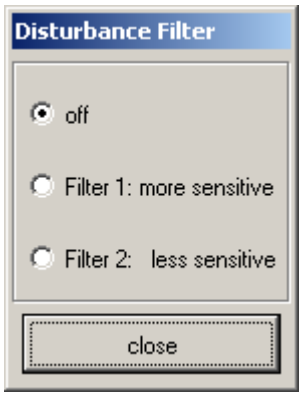


In the Audio Control window can be chosen whether and which acoustic signal should be audible. If **Channel 1** is chosen, only the signal is audible which is taken up by Sensor 1, the same applies to **Channel 2**. If **both** is selected, both signals are audible, with **mute** none. The volume of the selected channels can be regulated with the help of the **Volume** button.
The acoustic signal is ordinarily switched off while finishing a measurement (mute). If the hook beside **mute, when measure stopped** is removed, the signal remains furthermore audible.

(With the BC100 changes in this window have only consequences if the program simulates a measurement. Besides, the signal is given over the PC loudspeakers. Otherwise the channel choice and volume are regulated directly at the measuring instrument)

4.5.4. Disturbance Filter

In main screen there is an additional button Filter. With it is possible to activate an algorithm to suppress electro magnetically disturbances. Especially during coagulation these can occur. With this button there come the filter window, where the filter can be selected. There are two versions of the filter.



Filter 1 is a quiet sensitive algorithm. Advantage is, this version will detect the most disturbances and will them eliminate. Disadvantage, when the filter is active and there is no disturbance, also some bubble events can judged as disturbance and will be eliminated. So some bubble events can be lost. So filter 1 should be activated only when expecting disturbances (i.e. coagulation).
Filter2 works with an other algorithm to detect disturbance, it's not so sensitive like version1. Maybe some disturbance signals will counted as bubbles. On the other hand only some special bubble events will judged as disturbance (mostly when the peak is near the right or left end in the signal diagram).
Which version is to prefer depends from the disturbance signal and from the handling of the filter. When you activate the filter only for the time where disturbances occurs, version1 is to prefer. With a strong disturbance signal, maybe it's possible to activate version2 all the time. It would be more comfortable. The state of the filter is shown by the third smiley in the measurement screen.

5. Technical Details

5.1. Power Supply

Power Supply:	(Europe)	230V / 50Hz
	(USA)	115V / 60Hz
Fuse:	(Europe)	T250mA / 250V
	(USA)	T500mA / 250V

5.2. Measurement Range / Resolution

2 measurement channels

switchable :	Range1: 5-250 µm bubble size
	Range2: 10-500 µm bubble size
Flow rate:	0.4-6 l/min (for using 3/8" tubes)
Reference :	<10% (no or not enough reflected sound, measurement impossible)
	typical: 30%-70% with 3/8" plastic tube filled with water

5.3. Display

Switch able optical display of the bubble size or the reference signal per channel
Acoustical bubble signal, switch able between measurement channel 1 and 2

5.4. Software

BCView for Windows XP, Win7,
Data transfer via USB interface

5.5. Cleaning

Do not clean sensors with sharp detergents, do not dip into water. Clean the control unit only with a damp cloth.